K020963

APR 1 6 2002

BIOMET
CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.
56 East Bell Drive
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
Telephone: (219) 267-6639

Proprietary Name: HA Taperloc® Porous Femoral Stems & HA Taperloc® Porous Lateralized Femoral Stems

Common Name: Prosthetic Hip Joint – Hydroxyapatite (HA) Coated Porous Femoral Stem

Classification: Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate

Device Classification: Class II

Legally Marketed Device to which Substantially Equivalence is Claimed: Taperloc® Femoral Stem (K921301)

Device Description: The HA Taperloc® Porous Femoral Stems & HA Taperloc® Porous Lateralized Femoral Stems are the same as the predicate Taperloc® Femoral Stem (K921301), except for the additions of Hydroxyapatite Coating and additional sized femoral stems.

Indications for Use: The indications for the HA Taperloc® Porous Femoral Stems & HA Taperloc® Porous Lateralized Femoral Stems are for) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

Summary of Technologies: The HA Taperloc® Porous Femoral Stems & HA Taperloc® Porous Lateralized Femoral Stems' components-the materials, design, sizing, and indications are similar or identical to the predicate devices.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

Non-Clinical Testing: Mechanical Testing with an Engineering Justification determined that the HA Taperloc® Porous Femoral Stems & HA Taperloc® Porous Lateralized Femoral Stems' components presented no new risks and were, therefore, substantially equivalent to the predicate device.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2002

Ms. Dalene Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K020963
Trade Name: HA Taperloc® Porous Femoral Stem & HA Taperloc® Porous Lateralized Femoral Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: March 22, 2002
Received: March 25, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K020963

DEVICE NAME: HA Taperloc® Porous Femoral Stem & HA Taperloc® Porous Lateralized Femoral Stem

INDICATIONS FOR USE:

The HA Taperloc® Porous Femoral Stem & HA Taperloc® Porous Lateralized Femoral Stem are indicated for use for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020963

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